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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/461,709 12/14/99 BARCLAY

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EXAMINER

WARE, D

ART UNIT

PAPER NUMBER

1651

DATE MAILED:

09/27/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/461,709

Applicant(s)

Barclay

Examiner

Ware

Art Unit

1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 13, 2001
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38-93 is/are pending in the application.
- 4a) Of the above, claim(s) 38-52 and 67-93 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 53-66 is/are rejected.
- 7) ☒ Claim(s) 61-66 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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Claims 38-93 are presented for reconsideration on the merits.

The amendment filed July 13, 2001, has been received and entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The Information Disclosure Statement filed January 31, 2000, has been considered as previously informed and Applicant's gracious submission of the completed PTO-1449 Form as submitted with the response of July 13, 2001, is acknowledged. Therefore, an enclosed copy of the PTO-1449 indicating that the references have been considered is enclosed.

1. Claims 38-52 and 67-93 remain withdrawn from further consideration pursuant to 37 CAR 1.142(b), as being drawn to a nonelected invention(s), there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 5, March 19, 2001. These claims remain pending in the instant application.
2. Claim 58 remains rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for those reasons of record. It is noted that the strains have been deposited under the terms of the Budapest Treaty as indicated in US Patent No. 5,130,242. However, each case record is considered separately on its own merits. Therefore, deposit requirements must be met for each case. A copy of the declaration filed in the case for U.S. Patent No. 5,130,242 will satisfy this requirement providing that the strain accession numbers for deposit have not changed.

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Otherwise a new declaration providing the corrected accession numbers as well as the other information detailed in the prior action is requested.

3. Claims 53-56 and 59-66 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for euryhaline microorganisms of the genus *Thraustochytrium*, *Schizochytrium* and mixtures thereof, the specification does not reasonably provide enablement for any and all euryhaline microorganisms for use in the claimed method. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to carry out the process steps of the invention with any other genus of euryhaline microorganisms. Therefore, the enablement of the claimed invention is not commensurate in scope with these claims 53-56 and 59-66 for those reasons of record.

4. Applicant's arguments filed July 13, 2001, have been fully considered but they are not persuasive. The argument that the newly provided amendment remedies this issue is noted. However, the screening process detailed does not provide enablement for any other examples of euryhaline microorganisms other than those claimed in claims 57 and 58. In order to obtain the lipids as provided for in the claimed process there would be undue burden of experimentation for one of skill in the art to use any genus of a euryhaline microorganism without incurring undue hardship in the exercise of the screening process. As detailed in the newly provided for amendment to the instant specification the screening process is lengthy and exhaustive in its process for obtaining an appropriate euryhaline microorganism for carrying out the claimed process. Thus, one of skill would be hard pressed to find an appropriate one for which to carry

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out the claimed invention. Applicant's own patented subject matter (i.e. US Pat No. '242) requires the specific genus for carrying out the claimed inventions of the patented subject matter. Thus, it would appear that these genera are critical to the practice of the instantly claimed invention. Applicant's own specification does not teach any other specific genus and species for which the claimed method may be practiced with in order to obtain the lipids. Thus, the critical conditions as required by the claimed process are only enabled for these particular genera of euryhaline microorganisms. Thus, for those reasons of record and these presented herein this rejection is maintained.

5. Claims 53-66 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The method does not clearly set forth that the euryhaline microorganisms are biologically purified and thus, that the process is not being practiced with a product of nature. Thus, the language --biologically purified-- before "euryhaline microorganisms" in claim 53 at step (a) is requested.

Also claims 61-66 are objected to for using abbreviations and it is suggested to spell out at least the first occurrence of abbreviations in the claims.


No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is (703) 308-4245. The examiner can normally be reached on Mondays to Fridays from 9:30AM to 6:00PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


DEBORAH K. WARE
PATENT EXAMINER

Deborah K. Ware

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September 26, 2001